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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,042	06/29/2000	Kenneth B. Ain	50229-194	7670

7590

06/06/2005

McDermott Will & Emery  
600 13th Street N W  
Washington, DC 20005-3096

EXAMINER
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CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/606,042

**Applicant(s)**

AIN ET AL.

**Examiner**

Karen A. Canella

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 is/are allowed.
- 6) ☒ Claim(s) 20-22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

1. Claims 20 and 23 have been amended. Claims 20-24 are pending and under consideration.
2. The texts of sections of Title 35, U.S. Code not found in this action can be found in a previous action.
3. Claims 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreck et al (Journal of Clinical Endocrinology and Metabolism, 1994, Vol. 79, pp. 791-798). Claim 20 is drawn in part to a method for inducing the re-expression of a previously silenced endogenous gene encoding a human sodium-iodide symporter in a human thyroid carcinoma cell comprising administering to the cell sodium butyrate. Claim 21 embodies the method of claim 20 wherein the thyroid carcinoma cell is a follicular cell or a papillary cell. Claim 22 embodies the method of claim 20 where the re-expression is effected by demethylating the previous silenced endogenous gene or by inhibiting methylation in the cell.

Schreck et al disclose a method comprising the treatment of human follicular thyroid carcinoma cell line FTC-133 (page 792, first column, line 1 under the heading "Cell culture") with sodium butyrate (page 794, second column, lines 6-8 under the heading "Effects of RA..."). Schreck et al do not disclose that expression of the NIS is induced by the treatment, but both the specified cell type and chemical are in contact. It would be reasonably concluded that the interaction between the FTC-133 cells and the butyrate would result in the re-expression of NIS.

4. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by the abstract of Endean et al (FASEB Journal, 1995, Vol. 9, page A94).

Claim 24 is drawn to a method of restoring iodide transport to a human thyroid carcinoma cell comprising administering difluoromethylornithine. The abstract of Endean et al teaches that human thyroid papillary carcinoma cells (NPA-87) were contacted with difluoromethylornithine at a concentration which was non-toxic. The abstract does not disclose that expression of the NIS is induced by the treatment, but both the specified cell type and

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chemical are in contact. It would be reasonably concluded that the interaction between the NPA 87 cells and the difluoromethylornithine would result in the re-expression of NIS.

5. All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants arguments.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

5/31/2005

  
KAREN A. CANELLA PH.D.  
PRIMARY EXAMINER